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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,013	07/22/2003	Bridget Qiuying Cheng	03-6060a	8427
36596 7590 01/22/2007 LAW OFFICES OF J.F. LEE 17800 CASTLETON STREET SUITE 383 CITY OF INDUSTRY, CA 91748			EXAMINER MACAULEY, SHERIDAN R	
			ART UNIT 1609	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
3 MONTHS			01/22/2007	
			DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/625,013

Applicant(s)

CHENG, BRIDGET QIUYING

Examiner

Sheridan R. MacAuley

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:  
  
The term lactalbumin is spelled incorrectly throughout the application.  
  
The word "patient" on page 2, line 18 is spelled incorrectly.  
  
Appropriate correction is required.

### ***Claim Objections***

1. Claims 1 and 2 are objected to because of the following informalities: The term lactalbumin is spelled incorrectly. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether the claim is drawn to the composition with a ratio of 20 mg lysozyme to 180 mg lactalbumin, a specific weight makeup of 200 mg of the composition, or a capsule holding 20 mg lysozyme to 180 mg lactalbumin. Each is a reasonable interpretation of the claim, but each is somewhat different in scope, so the metes and bounds of the claim are not clear.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Valenti et al. (US Patent 5,830,489, issued November 3, 1998). Claim 1 recites a composition comprising about 10% by weight of lysozyme and 90% by weight lactalbumin. Valenti et al. disclose a protein preparation containing 5 to 90% albumins (including lactalbumin) and 2-90% lysozyme (column 3, lines 10-13; column 4, lines 1-9).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (Veterinary Immunology and Immunopathology, 1997, 56:85-96) in view of Sava (EXS, 1996, 75:433-49), and further in view of Valenti et al. (US Patent 5,830,489, issued November 3, 1998). Claim 2 recites a composition wherein the specific weight makeup in a capsule of 200 mg is 20 mg of lysozyme and 180 mg of lactalbumin. Wong et al. teach that alpha-lactalbumin has immunostimulatory effects in ruminants (abstract). Sava teaches that lysozymes have immunostimulatory effects in animals and humans (abstract). Valenti et al. disclose a protein preparation containing 5 to 90% albumins (including lactalbumin), 2-90% lysozyme and transferrin (column 3, lines 10-13; column 4, lines 1-9). Valenti et al. do not disclose a protein preparation containing lysozyme and lactalbumin without the addition of transferrin. Since lysozyme and lactalbumin were known at the time of the invention to have the same function, i.e. immunostimulation, it would be obvious to one skilled in the art to combine the two in a composition for human immunostimulation.

7. Further, Valenti et al. disclose a composition combining the lysozyme and lactalbumin in a protein composition, demonstrating that lysozyme and lactalbumin are compatible components. Lysozyme and lactalbumin are known to have immunostimulatory effects, as taught by Wong et al. and Sava. It would have been obvious to combine the two in a composition for human immunostimulation, as taught by the combined references discussed above. One skilled in the art would have a reasonable expectation of success in combining lysozyme and lactalbumin in a

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composition for human immunostimulation because the two have been shown to be compatible components by Valenti et al.

8. Regarding the limitation in claim 2 reciting the specific weight makeup in a capsule of 200 mg is 20 mg of lysozyme and 180 mg of lactalbumin, Valenti et al. disclose a packet containing 150 mg lactalbumin and 10 mg lysozyme (col. 9, lines 49-53). The values disclosed by Valenti et al. are similar in range to the values recited in claim 2, so it would have been obvious to one skilled in the art at the time of the invention to combine the two proteins in a composition of similar mass. Valenti et al. also disclose that the protein compositions can be administered in the form of a tablet (col. 4, line 63). The capsule disclosed by claim 2 is also similar or identical to the tablet disclosed by Valenti et al. It would have been obvious to one skilled in the art at the time of the invention to prepare a capsule containing a composition of lysozyme and lactalbumin. Therefore, it would have been obvious to one skilled in the art at the time of the invention to prepare a composition for human immunostimulation containing lysozyme and lactalbumin in a capsule of the specified mass with a reasonable expectation of success.

9. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Conclusion***

No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 727-0235. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM , ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

  
MARY E. MOSHER, PH.D.  
PRIMARY EXAMINER

1-16-07